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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR*	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,006	07/24/2001	Donald Shannon	VAS-4761CONDIV	5855

7590                    07/24/2002

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[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1733

DATE MAILED: 07/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/912,006	SHANNON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jessica L. Rossi	1733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 6/6/02, Amendment B, paper no. 6.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Response to Amendment***

1. This action is in response to the amendment dated 6/6/02. Claims 12-22 were canceled.

Claims 1-11 are pending.

2. The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art in the specification of the present application in view of House et al. (of record), as set forth in the previous office action, paper no. 4, has been withdrawn in light of Applicants arguments.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by the Admitted Prior Art in the specification of the present application.

With respect to claim 1, the Admitted Prior Art teaches a radially expandable tape-reinforced vascular graft comprising an expanded, sintered tubular PTFE base graft, having an expanded diameter and porosity, and an expanded, sintered PTFE reinforcing tape, having an expanded porosity, spirally wrapped around the base graft in its expanded diameter to form a combined tubular PTFE base graft (page 1, lines 19-29; page 2, lines 6-10).

As for the remaining limitations in present claim 1, it is noted that these are method steps that do not get any weight in an article claim unless one of ordinary skill in the art can show that the recited method steps would result in a materially different product.

Regarding claims 2-6, it is noted that method steps get no weight in an article claim unless one of ordinary skill in the art can show that the recited method steps would result in a materially different product.

***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-4 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art in view of Hiroyoshi (US 4678468) and House et al. (US 5026513; of record).

With respect to claim 1, if it is not taken that the tubular graft and reinforcing tape are expanded separately prior to wrapping the tape around the tubular graft and the method steps do not get weight in the article claim, the Admitted Prior Art is silent as to the expanded reinforcing tape being spirally wrapped around the tubular base graft in its expanded diameter and the base graft and tape being radially reduced in size.

It is known in the art to wind an expanded/stretched PTFE reinforcing tape around a PTFE tubular base graft in its expanded/stretched state, as taught by Hiroyoshi (column 10, lines 15-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to wrap the expanded reinforcing tape of the Admitted Prior Art around the tubular base graft in its expanded diameter because it is known in the art to separately expand/stretch a

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PTFE base graft and PTFE reinforcing tape prior to combining them, as taught by Hiroyoshi, wherein one skilled in the art reading the reference as a whole would have appreciated that wrapping the tape around the base graft prior to expansion of the base graft would restrict the degree of expansion of the base graft.

(House et al.) directed to making recoverable PTFE materials that can be used in vascular prosthesis, teaches that expanded, sintered PTFE articles subjected to compressive forces may be recoverable by compressing in a direction opposite to that which they were expanded (column 2, lines 1-11; column 3, lines 3-5 and 25-27 and 50-53; column 4, lines 4-16 and 62). It would have been obvious to one of ordinary skill in the art at the time the invention was made to radially compress (reduce) the PTFE combined graft of the Admitted Prior Art as taught by House et al. in order to provide a recoverable/re-expandable PTFE combined graft.

Regarding claim 2, the Admitted Prior Art is silent as to how expansion of the base graft is achieved and in what direction this expansion takes place. It would have been obvious to one of ordinary skill in the art at the time the invention was made to longitudinally expand the base graft of the Admitted Prior Art because such is known in the art, as taught by House et al. (column 2, line 67 – column 3, line 2), and only the expected results would have been achieved. Selection of a particular method of expansion would have been within purview of one of ordinary skill in the art at the time the invention was made because only the expected results would have been achieved.

Regarding claim 3, the Admitted Prior art is silent as to when sintering of the base graft takes place with respect to the expansion step. It would have been obvious to one of ordinary skill in the art at the time the invention was made to sinter the base graft following expansion of

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the base graft but prior to its being radially reduced in size because such is known in the art, as taught by House et al. (column 3, lines 3-5 and 24-26) and radially reducing the base graft after sintering allows the base graft to be re-expanded (column 2, lines 1-11).

Regarding claim 4, House et al. teaches compressing the expanded, sintered PTFE material by heating to a sintering temperature (column 3, lines 50-52).

Regarding claims 7-8, selection of a particular compressed (reduced) diameter for the base graft would have been within purview of one of ordinary skill in the art at the time the invention was made.

7. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art, Hiroyoshi and House et al. as applied to claim 1 above, and further in view of Dawson (US 3939243; of record).

Regarding claim 5, the Admitted Prior Art teaches it is known to use mandrels for processing grafts. House et al. teaches heating to a sintering temperature to compress/reduce the PTFE material (column 3, lines 50-52).

Regarding claim 6, the Admitted Prior Art as modified is silent as to the base graft and tape being radially reduced in size by positioning them around a series of progressively smaller cylindrical mandrels having an outside diameter smaller than an inside diameter of the base graft. Dawson, directed to treating plastic material such as PTFE tubes, teaches that radially shrinking plastic tubing incrementally produces tubes that will expand radially without extension in length (column 1, lines 40-65; column 4, lines 45-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use incrementally sized mandrels to radially reduce the graft of the Admitted Prior Art, as taught by Dawson, to produce grafts capable of

expanding radially without extension in length. House et al. teaches heating to a sintering temperature to compress/reduce the PTFE material (column 3, lines 50-52).

8. Claims 9-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art, Hiroyoshi and House et al. as applied to claim 1 above, and further in view of Schmitt et al. (US 6299636; of record).

Regarding claims 9-10, the Admitted Prior Art teaches it is known to anchor the graft to a vascular wall (page 2, line 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an anchoring mechanism, such as a stent, coupled to the graft because such is known in the art, as taught by Schmitt et al. (column 1, lines 33-40), wherein the stent serves to anchor the graft to the wall.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art, Hiroyoshi and House et al. as applied to claim 1 above, and further in view of Pinchuk (US 4798606; provided in IDS) and Popadiuk et al. (US 5556426).

Regarding claim 11, the Admitted Prior Art is silent as to spirally winding a reinforcing PTFE filament around the reinforcing tape. It is known in the art to spirally wind a reinforcing filament 34 around a graft 40 already having a reinforcement element (not shown) thereon to provide further reinforcement to the graft wherein spiral winding of the filament allows for the graft to maintain its expansion characteristics while also providing a high degree of kink resistance, as taught by Pinchuk (Figure 8; column 1, lines 21-23 and 44-53; column 4, lines 18-22 and 27 and 37-48; column 5, lines 18-20; column 6, lines 8-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to spirally wind a reinforcing filament around the graft of the Admitted Prior Art

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already having a reinforcement element thereon (reinforcing tape) because such is known in the art, as taught by Pinchuk, wherein the filament would provide further reinforcement to the graft without limiting graft expansion while allowing for a high degree of kink resistance.

As for the filament being PTFE, selection of a particular material would have been within purview of one of ordinary skill in the art at the time the invention was made. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a PTFE filament because it is known in the art to spirally wind a fluoropolymer reinforcing filament around a sintered, expanded fluoropolymer tubular graft, as taught by Popadiuk et al. (Figure 4; column 2, lines 1-2; column 5, lines 30-31; column 7, lines 46-47; column 9, lines 5-8 and 45-49; column 10, lines 24-27; column 11, line 1).

#### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 34-35 and 41 of U.S. Patent No. 5,928,279. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because the claims of the US Patent encompass the limitations of present claims 1 and 10.

12. Claims 1 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,843,173 in view of the Admitted Prior Art in the specification of the present application, or alternatively, the Admitted Prior art and Hiroyoshi.

The US Patent teaches all the limitations of present claims 1 and 9 but is silent as to the fluoropolymer base graft being expanded PTFE and the fluoropolymer reinforcing tape being expanded PTFE that is spirally wrapped around the base graft in its expanded state. It would have been obvious to one of ordinary skill in the art to use expanded PTFE for the base graft and reinforcing tape of '173 wherein the tape is spirally wrapped around the base graft in its expanded state because such is well known and conventional in the art as taught by the Admitted Prior Art, wherein the skilled artisan would have appreciated that selection of particular materials would have been within purview of the skilled artisan at the time the invention was made.

If it is not taken that the tape is wrapped around the graft in its expanded state, it would have been obvious to one of ordinary skill in the art to do so for the reasons set forth in paragraph 6 of the present office action with respect to the Hiroyoshi reference.

13. Claims 2-3 and 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,843,173 in view of the Admitted Prior Art, Hiroyoshi and House et al.

Regarding claims 2-3 and 7-8, Applicants are directed to paragraph 6 of the present office action.

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14. Claims 5-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,843,173 in view of the Admitted Prior Art, Hiroyoshi and Dawson.

Regarding claims 5-6, Applicants are directed to paragraph 7 of the present office action.

15. Claims 9-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,843,173 in view of the Admitted Prior Art, Hiroyoshi and Schmitt et al.

Regarding claims 9-10, Applicants are directed to paragraph 8 of the present office action.

16. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,843,173 in view of the Admitted Prior Art, Hiroyoshi and Pinchuk and Popadiuk et al.

Regarding claim 11, Applicants are directed to paragraph 9 of the present office action.

***Response to Arguments***

17. Applicant's arguments filed 6/6/02 have been fully considered but they are not persuasive.

18. On page 3 of the arguments, Applicants argue that the prior art cited by the examiner does not teach or suggest a reinforcing tape that is spirally wrapped around a tubular base graft in its expanded diameter as called for in present claim 1.

The examiner invites Applicants to reread the rejection of claim 1 set forth in paragraph 4 of the present office action. The examiner respectfully points out that the present specification states "The expanded PTFE from which the tubular base graft and the surrounding reinforcement

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tape are formed... (page 1, lines 22-23)" wherein the skilled artisan reading the present specification would have interpreted such language to mean that the graft is made from expanded PTFE and the tape is made from expanded PTFE prior to surrounding the expanded graft with the expanded tape. However, if it is not taken that the language of the present specification means just that, Applicants are invited to reread the rejection of claim 1 set forth in paragraph 6 of the present office action.

19. On page 3 of the arguments, Applicants argue that it would not have been obvious to spirally wind a reinforcing filament around the tape.

The examiner invites Applicants to reread the rejection of claim 11 as set forth in paragraph 9 of the present office action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jessica L. Rossi** whose telephone number is **703-305-5419**. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael W. Ball can be reached on 703-308-2058. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

*mBall*  
Michael W. Ball  
Examination Patent Examiner  
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Patent Examiner  
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July 18, 2002

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